



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

APR 30 2002

Mr. Shiming Han
Vice President
Wealth Express Industrial Ltd.
Block B1, 19/F Kailey Industrial Center
12 Fung Yip St. Chai Wan
Hong Kong

Dear Mr. Han:

This is to inform you that the completed notification, dated March 5, 2002, you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on March 11, 2002. Your notification concerns the substance called "Hirudo powder" that you assert is a new dietary ingredient. This new dietary ingredient notification is a resubmission of your notification concerning Hirudo powder, dated June 18, 2001 and follows our letter dated September 21, 2001, in response to that notification.

In accordance with 21 C.F.R § 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date (i.e., May 25, 2002), you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains "Hirudo powder."

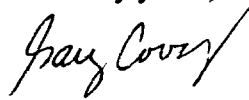
Please note that acceptance of this notification for filing is a procedural matter and, thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. As another procedural matter, your notification will be kept confidential for 90 days after the filing date. After June 9, 2002, the notification will be placed on public display at FDA's Docket Management Branch under docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public. Prior to June 9, 2002, you are welcome to identify in writing for us any information in your notification that you believe is proprietary or confidential. Our Freedom of Information

Page 2 – Mr. Shiming Han

Office will consider this when making the final decision about what information should be redacted from the notification before it is sent to Dockets.

Please contact us at (301) 436-1443, if you have any questions concerning this matter.

Sincerely yours,

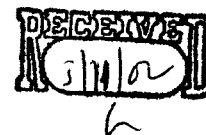
A handwritten signature in black ink, appearing to read "Gary Coody", with a long, sweeping horizontal stroke extending to the right.

Gary Coody, R.Ph.
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Wealth Express Industrial Ltd

March 5, 2002

Office of Special Nutritional
(HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c St. SW
Washington, DC 20204



Subject: About the Complete New Dietary Ingredient notification

Dear Officers:

After receiving the email notification from Mr. Gary Coody, we know that we had to submit a complete New Dietary Ingredient notification due to the delayed response of us in the supplemental information after the end of 75 days date for the original notification. Therefore, we made this new notification by adding the supplemental information to the original one. Please check it.

Best wishes,

Shiming Han

Vice President

Wealth Express Industrial Ltd.

Block B1, 19/F Kailey Industrial Center 12 Fung Yip St. Chai Wan
HongKong

Wealth Express Industrial Ltd

March 5, 2002

Office of Special Nutritional
(HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c St. SW
Washington, DC 20204

Subject: New Dietary Ingredient Notification For "Hirudo powder"

Dear Mr. Felicia B.Satchell:

As per the requirements stated within TITLE 21 Sec. 190.6, we provide with the below stated information:

1) Complete name of distributor for the new dietary ingredient:

Wealth Express Industrial Ltd.

Block B1, 19/F Kailey Industrial Center, 12 Fung Yip St. Chai Wan,
Hong Kong.

2) Complete name of the dietary ingredient:

Hirudo powder

3) A description of the dietary supplement expected to contain the subject material is best described according to proposed conditions suggested in the labeling of the dietary supplement.

The level of the dietary ingredient is 0.9g per day. Dietary ingredient of Hirudo powder in dietary supplement of Promoting Blood Circulation Capsule is 20%, i.e. 100mg Hirudo powder per 500mg capsule. Suggested dosage in the label is three capsules after each meal, i.e. 9 capsules per day, or 900mg Hirudo powder per day.

The ingredients in Promoting Blood Circulation Capsule have been traditionally used to support Qi and nourish Yin as well as to promote healthy blood circulation and immune function. According to traditional Chinese herbalism, this product is used for deficiency of both Qi and Yin, and is recommended for persons with purplish lips and tongue.

Due to the possible effect of abortive properties as said in literatures (Exhibit 1-3), Hirudo is not recommended for use in pregnant. And because of its relative strong effect of promoting blood circulation, persons with bleeding disorders or those who are taking blood-thinning medication or breast-feeding women are also not recommended for use. Therefore, the conditions of using this dietary supplement were written in the labeling as following:

WARNING: This product is not for use by persons with bleeding disorders or those taking blood-thinning medication. Not for use by pregnant or breast-feeding women. Always consult your physician before use.

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As for further explanation to product claims, we will report to FDA later as per requirements of 21CFR101.93.

4) Additional information that could contribute to demonstrate the safety of the use of Hirudo Powder in the dietary supplement, if being used under the conditions as written in the labeling of the dietary supplement.

Hirudo has been used in traditional Chinese medicine for thousands of years. Dosage of Hirudo is found that in medical literature early originated in the 1st Century, *Synopsis of the Golden Chamber* records a dosage of 30 Hirudos per day, taken in soup with other ingredients. *Pen-ts'ao Kan-mu* published around the year of 390 also describes the dosage of Hirudo.

Also extensively seen is Hirudo's dosage in current Chinese medicinal literatures, e.g. the *Pharmacopoeia of the People's Republic of China* (Edition 1995) (Exhibit 1) records a *Hirudo dosage of 1.5~3g per day*; *Traditional Chinese Medicinal Science* (Exhibit 2) carries the same record; the *Clinical Traditional Chinese Medicinal Science* (Exhibit 3) makes more detailed explanation on Hirudo dosage: *[Dosage for Reference] for internal taking, 3~5g each day. For drenched taking, 0.3~0.5g each time*, in addition, it also illustrates 9 cases of Hirudo use and their dosages.

Till now, there is not any document had been found on the time limitation of hirudo powder usage in TCM or TCD textbooks of ancient Chinese medical books and modern pharmacopoeia. In China, Chinese people have been adopting hirudo powder as ingredients of TCDs to treat some diseases for a millenium. Some common-used cases were listed in literatures of Exhibits 1-3. And the duration of 4-6 weeks, as mentioned in Exhibits 1-3, does not mean a time limit of using these formulas, but the period of treatment. Owing to slow effect release of TCD products, an intake course usually takes several periods of treatment.

Hirudin element in hirudo is a finding of modern medicine in the 20th century, which is not seen in books on TCM. Hirudo element in TCD products is a powder made through the following processes: grinding dried hirudo into powder of about 100 meshes; stewing the powder with water; filtering; thickening; drying it with vacuum; regrinding to powder of about 100 meshes. Archives of TCM, TCD and China pharmacopoeia unanimously do not pose requirements or limit to some contents (hirudin or enzyme) of hirudo.

Source for hirudo powder is stable and is under quality requirements of China pharmacopoeia. Producer produces this product under requirements of GMP. Every batch of this product has undergone strict examination before ex-works so as to guarantee the product quality.

Promoting Blood Circulation Capsule had been applied by physicians in Chinese Academy of TCM since 1978 for over twenty years. Some users have been taking this

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capsule for more than a decade without any report of adverse effect. In the year 1995, this capsule came into market nationwide and from then on no complaints or report on adverse effects have ever been received by researchers and inventors, the pharmaceutical producer, governmental administrators, and consumer protection associations. See Exhibit 4 and 5 for details.

Before submitting this product for examination by the State Drug Administration of China in 1995, researchers had conducted acute toxicological experiment and chronic toxicological experiment in animals. Those experiments reveal that this product is void of poisonous or side effects and therefore can be taken for long time. The experiment report is enclosed here as Exhibit 6 and 7.

Note: this experiment report is confidential, no disclosure is permitted without authorization.

In this scenario, we can conclude the recommended dosage in the label of the dietary supplement is lower than those recorded in above-mentioned literatures, which shall be deemed safety to health, if being used under the conditions as written in the labeling of the dietary supplement.

For evidence of this notification, we make reference to seven (1-7) exhibit documents and an eighth (8) exhibit, which is a compilation of published articles pertinent to the issue. All exhibits are enclosed herein and presented in no order of significance. In the case of exhibits originally composed in the Chinese language, we also enclose the original copy in Chinese for your inspection.

Exhibit 1: A translation from Chinese.

Pharmacopoeia of the People's Republic of China, Edition 1995 Part I

Compiled by Pharmacopoeial Committee of the Ministry of Health, the People's Republic of China. Page:67

Exhibit 2: A translation from Chinese.

Traditional Chinese Medicinal Science

Compiled by *Yan Zhenghua, Wong Weijian, Gao Xuemin, Pang Junzhong, Shen Liansheng, Gong Shusheng* and *Yao Kuanlu* Beijing College of Traditional Chinese Medicine October 1979 page:389

Exhibit 3: A translation from Chinese.

Clinical Traditional Chinese Medicinal Science

Chief Compilers: *Wong Weiliang, Fang Shuting* Henan Sci-tech Publishing House. Page:936--940

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Exhibit 4: A translation from Chinese.

"Specification of Promoting Blood Circulation Capsule"

Prof. Lin Lan

Chinese Academy for TCM (Traditional Chinese Medicine).

Exhibit 5: A translation from Chinese.

"About Promoting Blood Circulation Capsule"

Mr. Cao Shushan

Manufacture & Technology department

Siping Pharmaceutical Co., Ltd. (CHINA)

Exhibit 6: A translation from Chinese.

"Material of Acute Toxicity Test in Animals and Literature"

Institute of Basic Researches & Institute of Pharmacology, China Academy of Traditional Chinese Medicine

Exhibit 7: A translation from Chinese.

"Material of Long-term Toxicity Test in Animals and Relevant Literature"

Ni Ping, Sun Mingjie, Zhou Yanhua. Department of Pharmacology, Institute of Basic Theories, China Academy of Traditional Chinese Medicine

Wang Anmin, Zeng Xiaolian, Lu Aiping. Department of Pathology, Institute of Basic Theories, China Academy of Traditional Chinese Medicine

Exhibit 8: a publication on the Internet.

Medicinal Leeching --Past and Present ThromboSite

Newsletter Volume 1, Issue 3 (January, 1999)

http://www.thrombosite.com/tsnews/tsnews1_3.html

5) The signature of the person designated by the distributor of the dietary ingredient.


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This letter and its attachments are respectfully submitted and intended to be a premarket notification to the FDA. In due course, we request a receipt acknowledgement.

Of course, if there are questions or clarifications needed for your review and consideration of these documents please immediately contact the undersigned and I will endeavor to address your questions and/or additional requirements.

Sincerely

A handwritten signature in black ink that reads "Shiming Han". The signature is written in a cursive, flowing style.

Shiming Han
Vice President

Enclosures